

REMARKS

Reconsideration of the allowability of the present application in view of the above amendments and the following remarks is requested respectfully.

Discussion of the Amendments

The descriptive portion of the application has been amended to add generic terminology to accompany trade names. No new matter has been added. A ® has not been added after Tonsil Supreme and Filtrol as these are not registered trademarks.

Discussion of the Claims

No claims have been added, cancelled, or amended with the present Reply. The claims presently pending are Claims 1 to 13, 15, 16, 18 to 23, 31, 61, 72, and 75 to 78.

Discussion of the Examiner's Rejection of
Claims 1, 2, 4 to 10, 12, 13, 15, 16, 18 to 23, 72, and 77 to 79 Under Section 103(a)

In the Action, the Examiner rejected Claims 1, 2, 4 to 10, 12, 13, 15, 16, 18 to 23, 72, and 77 to 79 as being unpatentable over U.S. Patent No. 4,093,540 to Sen Gupta and U.S. Patent No. 5,336,794 to Pryor et al. Sen Gupta discloses a process for refining glyceride oil which comprises solvating the oil, ultrafiltering the solution, and contacting the solution with silica. Sen Gupta claims that the process may be used to refine marine oil (but does not include an actual working example involving refining marine oil). Pryor et al. discloses a process for refining glyceride oil comprising contacting the oil with silica and with bleaching clays. According to the Examiner, one skilled in the art would have been

motivated to combine the teaching of Sen Gupta of a process for refining glyceride oil with the teaching of Pryor et al. of the use of bleaching clays in the refining process to arrive at applicant's invention.

The Examiner's rejection is traversed respectfully. In order to establish a *prima facie* case of obviousness, the combined disclosures of the cited art must teach or suggest each element of the claims. MPEP §2142. Independent Claim 1, from which Claims 2, 4 to 10, 12, 13, 15, 16, 18 to 23, 72, and 77 to 79 depend, distinguishes over the combined disclosures of Sen Gupta and Pryor et al. in that it recites the step of contacting marine oil which comprises crude oil or foundation oil with silica and the step of contacting marine oil which comprises crude oil or foundation oil with bleaching clays. The combined disclosures of the cited art do not teach or suggest such steps. In Sen Gupta, it is a solution formed by solvating crude oil that is contacted with silica. Crude oil or foundation oil itself is not contacted with silica. Pryor et al. does teach contacting crude oil with silica and bleaching clays but does not teach the use of a marine oil comprising crude oil. Rather, it contains only a general disclosure that glyceride oils, including animal oils, may be used in the processes therein. As stated previously in the above Reply, marine oils present a special case as they are typically more contaminated than other oils. Contaminants are introduced into the marine oil in the course of rendering the animal. Oil-soluble contaminants from gut contents and, in some cases, also compounds from the fish skin enter the oil in addition to compounds derived from proteinaceous and mucilaginous material associated with the body oils and heavy metals and oxidation products. Many of the above contaminants, if not thoroughly removed, undergo reactions at high deodorizing temperatures. Traces of some of these contaminants produce colored compounds and odoriferous compounds, in addition to color and flavor natively present in the oil. The flavor

and flavor stability of the oil is also impaired by these contaminants. The highly reactive nature of the polyunsaturated fatty acids in fish oil makes it especially important to remove the above-mentioned contaminants from the oil very thoroughly in order to achieve a flavorless oil of adequate flavor stability for human consumption. As such, it is quite clear that marine oils present a special case and the general disclosure in Pryor et al. that the process therein may be used in refining glyceride oils, including animal-derived glyceride oils, does not constitute a teaching or suggestion that it may be used in refining marine oil.

Given the above, it is abundantly clear that the combined disclosures of the cited art do not teach or suggest the step of contacting marine oil comprising crude oil or foundation oil with silica or the step of contacting marine oil comprising crude oil or foundation oil with bleaching clays.

Applicant requests respectfully the withdrawal of the Examiner's rejection.

Discussion of the Examiner's Rejection of Claim 3 Under Section 103(a)

In the Action, the Examiner rejected Claim 3 as being unpatentable over Sen Gupta and Pryor et al. in view of Wanasundara et al., *Journal of Food Lipids*, 5: 29-41 (1998). Sen Gupta and Pryor et al. were cited for the same reasons as above. The Examiner cited Wanasundara et al. as suggesting the undesirability of using a deodorization step as it may lead to the elimination of tocopherols which serve to protect the components of marine oil. The Examiner considers the combined disclosures to, therefore, suggest a process which consists of contacting foundation oil (the Examiner considers the ultrafiltration step of Sen Gupta as a step in the creation of the initial foundation oil) with silica and bleaching clay, with the disclosure of Wanasundara et al. motivating one skilled in the art to forgo any additional step.

The Examiner's rejection is traversed respectfully.

In the first instance, applicant disagrees with the Examiner's logic. Even if, as the Examiner alleges, Wanansundara et al. would motivate one skilled in the art to forgo the deodorization step, it does not suggest one skilled in the art to forgo any other step.

Regardless of the above, however, traversal is based on the fact that the Examiner has failed to establish a *prima facie* case of obviousness as the combined disclosures of the cited art do not teach or suggest the step of contacting marine oil which comprises crude oil or foundation oil with silica or the step of contacting marine oil which comprises crude oil or foundation oil with bleaching clay. As stated above, the combined disclosures of Sen Gupta and Pryor et al. do not teach or suggest such steps. Wanasundara et al. does not remedy this deficiency. Accordingly, the combined disclosures of the cited art fail to teach or suggest all the elements of the rejected claim.

Applicant requests respectfully the withdrawal of the Examiner's rejection.

Traversal of the Examiner's Rejection of Claims 31, 75, 76, and 80 Under Section 103(a)

In the Action, the Examiner rejected Claims 31, 75, 76, and 80 as being unpatentable over Sen Gupta and Pryor et al.

Claims 31, 75, 76, and 80 define a refined oil prepared using a process comprising the steps of contacting a marine oil comprising crude oil or foundation oil with silica and contacting a marine oil comprising crude oil or foundation oil with bleaching clays. As noted above, Sen Gupta discloses a completely different process from the one used in the present invention. In the process of Sen Gupta, crude oil is subject to being solvated with organic solvent to form a solution comprising phospholipid micelles. This solution is then either contacted with silica and then fractionated using ultrafiltration or the solution is first fractionated using ultrafiltration and then the fraction containing the oil is contacted with silica. In either case, the crude oil itself is not contacted with silica but rather a solution formed after the crude oil is mixed with a solvent is contacted with silica. It should be noted also that the amount of solvent used is significant. For example, on column 4, lines 36 to 38, Sen Gupta notes that preferably the oil makes up only 10 to 50%, more preferably 20 to 30% by weight of the resulting solution. It should be noted also that Sen Gupta discloses the use of greater amounts of silica than are typically used in the practice of applicant's invention. In the disclosed Examples in Sen Gupta, the ratio of the total lipid to silica is 4:1. By contrast, the present invention typically uses between about 0.01% to about 3% silica by weight of oil.

While the above differences relate to the process used to produce the claimed product, it is intuitive that the product resulting from such a vastly different process must be vastly different as well. In fact, this is borne out by comparing the organoleptic test results of the products. Sen Gupta describes a scale on which oils are given a score of up to 8 with 8 representing "an excellent oil, completely neutral in taste", 3 representing "an extremely bad oil, unpalatable and unsuitable for human consumption", and 5 being the limit of acceptability. In

Example 3 of Sen Gupta, the resulting product received a score of 6.2 or 6.6, depending on the steps used in the process, which is marginally above that of conventionally refined crude oil (6). Accordingly, it appears that the product of the Sen Gupta process is not bland and odorless. By contrast, the oil of the present invention, as shown in Examples 1 and 2 of the present application, has a completely bland taste.

Given the above, it is abundantly clear that the product resulting from Sen Gupta is vastly different from the product of the present invention. While Pryor et al. discloses the additional step of bleaching the oil using bleaching clays, nowhere in Pryor et al. is there any teaching or suggestion that the use of this step in conjunction with the process of Sen Gupta would result in applicant's bland tasting product. Accordingly, applicant's invention is non-obvious in view of the cited art.

Applicant requests respectfully the withdrawal of the Examiner's rejection.

Traversal of the Examiner's Rejection of Claim 11 Under Section 103(a)

The Examiner rejected Claim 11 as being unpatentable over Sen Gupta and Pryor et al. in view of Wanasundara et al. and further in view of U.S. Patent No. 4,780,309 to Geria et al. and U.S. Patent No. 4,678,808 to Ward et al. The combined disclosures of Sen Gupta, Pryor et al., and Wanasundara et al. are cited as disclosing a refining process comprising contacting marine oil with silica and with bleaching clays. Geria et al. and Ward et al. are cited as teaching the desirability of using fish oils in the treatment of diseases and conditions. According to the Examiner, one skilled in the art would have been motivated by the above art to refine fish oil by contacting fish oil comprising crude or foundation oil with silica and with bleaching clays.

The Examiner's rejection is traversed respectfully. In order to establish a *prima facie* case of obviousness, the combined disclosures of the cited art must teach or suggest each element of the claim. MPEP §2142. Claim 11 distinguishes over the combined disclosures of the cited art in that it recites the step of contacting fish oil which comprises crude oil or foundation oil with silica and the step of contacting fish oil which comprises crude oil or foundation oil with bleaching clays. The combined disclosures do not teach or suggest such steps. In Sen Gupta, it is a solution formed by solvating crude oil that is contacted with silica. Crude oil or foundation oil itself is not contacted with silica. Pryor et al. does teach contacting crude oil with silica and bleaching clays but does not teach the use of a marine oil comprising crude oil. Rather, it contains only a general disclosure that glyceride oils, including animal oils, may be used in the processes therein. As stated previously in the above Reply, marine oils present a special case as they are typically more contaminated than other oils. Contaminants are introduced into the marine oil in the course of rendering the animal. Oil-soluble contaminants from gut contents and, in some cases, also compounds from the fish skin enter the oil in addition to compounds derived from proteinaceous and mucilaginous material associated with the body oils and heavy metals and oxidation products. Many of the above contaminants, if not thoroughly removed, undergo reactions at high deodorizing temperatures. Traces of some of these contaminants produce colored compounds and odoriferous compounds, in addition to color and flavor natively present in the oil. The flavor and flavor stability of the oil is also impaired by these contaminants. The highly reactive nature of the polyunsaturated fatty acids in fish oil makes it especially important to remove the above-mentioned contaminants from the oil very thoroughly in order to achieve a flavorless oil of adequate flavor stability for human consumption. As such, it is quite clear that marine oils present a special case and the general disclosure in

Pryor et al. that the process therein may be used in refining glyceride oils, including animal-derived glyceride oils, does not constitute a teaching or suggestion that it may be used in refining marine oil. Wanasundara et al., Geria et al., and Ward et al. do not remedy the above deficiencies.

Given the above, it is abundantly clear that the combined disclosures of the cited art do not teach or suggest the step of contacting fish oil comprising crude oil or foundation oil with silica or the step of contacting fish oil comprising crude oil or foundation oil with bleaching clays.

Applicant requests respectfully the withdrawal of the Examiner's rejection.

Traversal of the Examiner's Rejection of Claims 61 and 82 Under Section 103(a)

The Examiner rejected Claims 61 and 82 as being unpatentable over Sen Gupta and Pryor et al. in view of Wanasundara et al. and further in view of Geria et al. and Ward et al. The references are cited for the same reasons as discussed above.

Claims 61 and 82 define a method for using a refined oil prepared using a process comprising the steps of contacting a marine oil comprising crude oil or foundation oil with silica and contacting a marine oil comprising crude oil or foundation oil with bleaching clays. As noted above, Sen Gupta discloses a completely different process from the one used in the present invention. In the process of Sen Gupta, crude oil is subject to being solvated with organic solvent to form a solution comprising phospholipid micelles. This solution is then either contacted with silica and then fractionated using ultrafiltration or the solution is first fractionated using ultrafiltration and then the fraction containing the oil is contacted with silica. In either case, the crude oil itself is not contacted with silica

but rather a solution formed after the crude oil is mixed with a solvent is contacted with silica. It should be noted also that the amount of solvent used is significant. For example, on column 4, lines 36 to 38, Sen Gupta notes that preferably the oil makes up only 10 to 50%, more preferably 20 to 30% by weight of the resulting solution. It should be noted also that Sen Gupta discloses the use of greater amounts of silica than are typically used in the practice of applicant's invention. In the disclosed Examples in Sen Gupta, the ratio of the total lipid to silica is 4:1. By contrast, the present invention typically uses between about 0.01% to about 3% silica by weight of oil.

While the above differences relate to the process used to produce the claimed product, it is intuitive that the product resulting from such a vastly different process must be vastly different as well. In fact, this is borne out by comparing the organoleptic test results of the products. Sen Gupta describes a scale on which oils are given a score of up to 8 with 8 representing "an excellent oil, completely neutral in taste", 3 representing "an extremely bad oil, unpalatable and unsuitable for human consumption", and 5 being the limit of acceptability. In Example 3 of Sen Gupta, the resulting product received a score of 6.2 or 6.6, depending on the steps used in the process, which is marginally above that of conventionally refined crude oil (6). Accordingly, it appears that the product of the Sen Gupta process is not bland and odorless. By contrast, the oil of the present invention, as shown in Examples 1 and 2 of the present application, has a completely bland taste.

Given the above, it is abundantly clear that the product resulting from Sen Gupta is vastly different from the product of the present invention. While Pryor et al. discloses the additional step of bleaching the oil using bleaching clays, nowhere

in Pryor et al. is there any teaching or suggestion that the use of this step in conjunction with the process of Sen Gupta would result in applicant's bland tasting product. Wanasundara et al., Geria et al., and Ward et al. do not remedy this deficiency. As the refined oil is not obvious over the cited art, methods for using it are not obvious over the cited art. Accordingly, applicant's invention is non-obvious in view of the cited art.

Applicant requests respectfully the withdrawal of the Examiner's rejection.

Traversal of the Examiner's Rejection of Claim 81 Under Section 103(a)

The Examiner rejected Claim 81 as being unpatentable over Sen Gupta and Pryor et al. in view of Wanasundara et al. and further in view of Geria et al. and Ward et al. The references are cited for the same reasons as discussed above.

Claim 81 defines a composition comprising a refined oil prepared using a process comprising the steps of contacting a marine oil comprising crude oil or foundation oil with silica and contacting a marine oil comprising crude oil or foundation oil with bleaching clays. As noted above, Sen Gupta discloses a completely different process from the one used in the present invention. In the process of Sen Gupta, crude oil is subject to being solvated with organic solvent to form a solution comprising phospholipid micelles. This solution is then either contacted with silica and then fractionated using ultrafiltration or the solution is first fractionated using ultrafiltration and then the fraction containing the oil is contacted with silica. In either case, the crude oil itself is not contacted with silica but rather a solution formed after the crude oil is mixed with a solvent is contacted with silica. It should be noted also that the amount of solvent used is significant. For example, on column 4, lines 36 to 38, Sen Gupta notes that preferably the oil makes up only 10 to 50%, more preferably 20 to 30% by weight of the resulting

solution. It should be noted also that Sen Gupta discloses the use of greater amounts of silica than are typically used in the practice of applicant's invention. In the disclosed Examples in Sen Gupta, the ratio of the total lipid to silica is 4:1. By contrast, the present invention typically uses between about 0.01% to about 3% silica by weight of oil.

While the above differences relate to the process used to produce the claimed product, it is intuitive that the product resulting from such a vastly different process must be vastly different as well. In fact, this is borne out by comparing the organoleptic test results of the products. Sen Gupta describes a scale on which oils are given a score of up to 8 with 8 representing "an excellent oil, completely neutral in taste", 3 representing "an extremely bad oil, unpalatable and unsuitable for human consumption", and 5 being the limit of acceptability. In Example 3 of Sen Gupta, the resulting product received a score of 6.2 or 6.6, depending on the steps used in the process, which is marginally above that of conventionally refined crude oil (6). Accordingly, it appears that the product of the Sen Gupta process is not bland and odorless. By contrast, the oil of the present invention, as shown in Examples 1 and 2 of the present application, has a completely bland taste.

Given the above, it is abundantly clear that the product resulting from Sen Gupta is vastly different from the product of the present invention. While Pryor et al. discloses the additional step of bleaching the oil using bleaching clays, nowhere in Pryor et al. is there any teaching or suggestion that the use of this step in conjunction with the process of Sen Gupta would result in applicant's bland tasting product. Wanasundara et al., Geria et al., and Ward et al. do not remedy this deficiency. As the refined oil is not obvious over the cited art, a composition

comprising such an oil is not obvious over the cited art. Accordingly, applicant's invention is non-obvious in view of the cited art.

Applicant requests respectfully the withdrawal of the Examiner's rejection.

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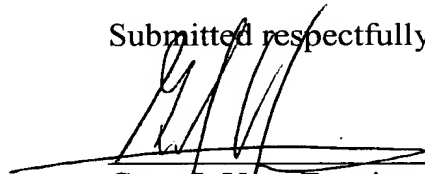
Art Unit 1651

Conclusion

In view of the above amendment and remarks, an early and favorable Action is requested respectfully.

The commissioner is hereby authorized to charge any fees associated with this communication to Deposit Account No. 19-5425. A duplicate of this letter is attached.

Submitted respectfully,



Gene J. Yao, Esquire
Reg. No. 47,193
Attorney for Applicant

Synnestvedt & Lechner
2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107-2950
(215) 923-4466